REMARKS

Applicant has considered the non-final office action mailed December 1, 2008, in connection with the above-identified patent application.

Information Disclosure Statement ('IDS') Filed July 30, 2008

Applicant reminds the Examiner of the information disclosure statement, including a PTO-1449-form, filed in the instant application on July 30, 2008, concurrently with Applicant's prior response on the merits. Applicant does not see that the Examiner has acknowledged receipt of that IDS and provided Applicant with a copy of the 1449-form showing initialed/inlined entries to confirm that the Examiner has considered the references listed thereon. Applicant therefore requests that the Examiner considers those references and confirms the same at his earliest convenience.

Statement of Substance of Interview held February 26, 2009

Applicant's representative, the undersigned, thanks Examiner Ramdhanie and Supervisory Examiner Griffin ("the Examiners") for courtesies extended to Applicant's representative on the occasion of a telephonic interview ("the Interview" hereinafter) to discuss rejections of record, on February 26, 2009. Also present at the interview, by telephone, were Dr. Kalyan Handique, first-named inventor and Chief Technology Officer of HandyLab, Inc. (assignee of the instant application), and Fish & Richardson P.C. Associate, Keeley I. Vega. Applicant now provides a statement of substance of the interview, as required by MPEP § 713.04.

During the interview, those present discussed the rejections of record under 35 U.S.C. §§ 102 and 103 and offered remarks responsive thereto, in particular a clarification of whether the Parunak reference could be properly cited against Applicant's claims under 35 U.S.C. § 103, and Applicant's view that Parunak does not describe the structure recited in Applicant's claims. Agreement was not formally reached, but the Examiners expressed willingness to take Applicant's remarks under consideration.

Amendments to the Claims

Claims 1-14, 16, and 18-21 are pending in the instant Application, prior to entry of the instant amendments.

Applicant amends, herewith, claim 1 to incorporate the subject matter of claims 2 and 6. (S*ee also*, *e.g.*, specification at page 22, lines 20-21 ("Fluid that enters chamber 699, such as by passing through retention member 694, decreases a free volume thereof and increases a pressure therein.").) Claim 1 is further amended to recite "a gate configured to open a channel downstream of the reservoir thereby decreasing the pressure within the reservoir," as described in the specification as filed at, *e.g.*, page 21, lines 26-28 and page 23, lines 15-19 ("[t]o prepare an enriched particle-containing fluidic sample, gate 616 is actuated to the open state thereby providing a passage for material to exit chamber 699. The relatively greater pressure within the chamber drives fluid therein through retention member 694 and into cavity 691 of enrichment region 602.").

Claims 1, 3, 4, and 8 are amended to address various aspects of antecedent basis.

Claim 9 is amended to recite "a reservoir in communication with the retention member configured so that a first liquidic portion of a particle-containing liquid sample received therein enters the reservoir along an entry path including a first surface of the retention member and particles of the particle-containing liquid sample are thereby retained by the retention member." Support for this amendment is found in the Specification at, for example, page 3, lines 8-12 and page 23, lines 4-6. Claim 9 is also amended to recite "a gate having an open configuration wherein a subset of the first liquidic portion exits the reservoir along an exit path including the first surface of the retention member, wherein the entry path is substantially opposite the exit path," as described in the specification as filed at, *e.g.*, page 16, lines 1-4 and page 23, lines 15-19.

Claim 10 is amended to make consistent terminology where other usage within the application as filed may differ and where it would be clear which term is correct.

Claim 12 is amended to address various aspects of antecedent basis.

Claim 13 is amended to correspond with the amendment made in claim 12 and to address various aspects of antecedent basis.

Claims 16 and 20 are amended to make consistent terminology where inconsistent with other usage within the application as filed and where it would be clear which term is correct.

Claim 19 is amended to address various aspects of antecedent basis.

Claim 20 is further amended to recite a reservoir "configured to receive at least some of a first liquidic portion of the particle-containing liquidic sample." Support for the amendment can be found in the Specification at, for example, page 23, lines 4-6.

Claim 21 is amended to correspond with the amendment made in claim 20, and to recite aspects of a thermally responsive substance, as found at the specification at *e.g.*, page 12, lines 4 – 6.

Claims 2, 6 and 14 are cancelled herein without prejudice. Applicant reserves the right to pursue the subject matter of claims 2, 6 or 14 in subsequent prosecution of the instant application, or in one or more continuations or divisionals thereof.

Accordingly, no new matter is introduced by way of the new claims herein and entry thereof is respectfully requested.

Objections to the Claims

The Examiner has objected to claim 8 as recited to be dependent on claim 8. Applicant herein amends claim 8 to address this issue of antecedent basis. As amended, claim 8 is recited to be dependent on claim 7. Accordingly, Applicant respectfully requests that the objection to claim 8 be removed.

REJECTIONS OF THE CLAIMS

Rejections under 35 U.S.C. § 102

The Examiner has rejected claims 1-6, 9, 14, and 18 under 35 U.S.C. § 102(a) as allegedly being anticipated by Parunak et al. (WO03/012406) (hereinafter "Parunak"). Applicant respectfully traverses the rejection.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Additionally, "[t]he identical invention must be shown in as complete detail as is contained in the

... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Applicant respectfully points out that Parunak neither teaches each and every element of Applicant's claims, nor describes Applicant's invention in complete detail.

Claim 1 as amended herein by incorporating subject matter of claims 2 and 6, recites "a reservoir in communication with the retention member and configured to receive at least some of the first liquidic portion separated from the particles, wherein a pressure within the reservoir increases upon receiving the first liquidic portion." Claim 1 further recites "a gate configured to open a channel downstream of the reservoir thereby decreasing the pressure within the reservoir so that at least some of the separated particles recombine with a subset of the first liquidic portion separated from the particles." (*Id.* at page 23, lines 15-18.) Applicant finds no such disclosure in Parunak.

The Examiner submits that the flow through member of Parunak is not "one-way" only, and therefore argues that the liquid may flow back during the use of the actuator of Parunak thereby recombining at least some of the first portion of the liquid separated from the particles. However, Applicant's claim does not recite an actuator to recombine separated particles with a portion of the liquid. Furthermore, Parunak does not disclose any device capable of manipulating the flow of liquid such that the liquid can flow back through a flow through member. Instead, Parunak (at page 14) discloses introducing a particle-containing fluid into an input port 180, wherein the fluid passes through a flow through member 900, thereby exiting enrichment zone 931, and particles accumulate within the zone. Parunak further describes an actuator 168 that provides a motive force to move the enriched particle sample *downstream* from enrichment zone 931, *i.e.*, in the same direction as it was originally displaced. (Parunak, page 15) Parunak does not disclose causing the particle-containing fluid to pass through flow through member 900 in a second, opposite direction, thereby recombining a subset of the particle-containing fluid with the separated particles, as recited in claim 1. In fact, Parunak discloses that: "[t]he flow through member and the fluid therein substantially prevents gas from escaping the enrichment zone. Thus, the resulting gas pressure moves the enriched particle sample downstream from the enrichment zone 931." (Parunak, page 15.) Parunak also discloses that the enriched particle sample is moved downstream with essentially no dilution thereof. (Parunak,

page 15.) Therefore, Parunak discloses that the flow through member permits flow in only one direction such that there is no dilution of the enriched particle sample upon movement downstream.

Thus, Applicant submits that claim 1 is not anticipated by Parunak. Furthermore, Applicant submits that claims 3, 4, and 5 are not anticipated by Parunak at least by virtue of their dependency on claim 1. Claims 2 and 6 have been cancelled, thereby mooting the rejection with respect to those claims.

Claim 9, as amended herein, recites a microfluidic device having an enrichment region that includes a retention member, a reservoir, and a gate. The gate is configured to cause a subset of the first liquidic portion to exit the reservoir along an exit path including the first surface of the retention member that is substantially opposite an entry path including the first surface of the retention member. Again, Parunak does not describe such a structure. In fact, in Parunak, there is only a description of an actuator that is configured to move enriched sample in the same direction that it has already been traveling (see, *e.g.*, FIG. 3 of Parunak, and accompanying description).[1]

Claim 14 has been cancelled herein.

With respect to claim 18, the Examiner contends that Parunak teaches a mass of thermally responsive substance (TRS) positioned in a channel downstream from the lysis chamber. The Examiner points to Figure 4 and identifies Item 160 as the lysis chamber and submits that Item 204 is downstream from the chamber. Applicant respectfully disagrees with the Examiner's characterization of Figure 4 and the related teachings. As shown in Figure 4, valve 204 is in fact *upstream* from the lysing module 160. Similarly, Parunak teaches that a microdroplet moves in the direction from microdroplet preparation module 158 to lysing module 160. (Parunak, page 18, lines 7-8.) Thus, Parunak does not teach a mass of TRS positioned in a

[1] The Examiner submits that Applicant's previous argument (Response to Office Action, July 30, 2008) that claim 9 recites a limitation of a "pressure activator" is incorrect. Applicant's argument contained a clerical error and should have read "pressure *actuator*", as should have been apparent from both the claim language at the time, as well as the other remarks in the response. However, in light of the amendment made to claim 9 herein, this aspect of the Examiner's rejection is moot.

channel downstream from a lysis chamber configured to inhibit downstream passage of material as recited by claim 18 and to pass downstream upon being heated.

Accordingly, the rejected claims, as originally filed or as amended herein, are not anticipated by Parunak, and Applicant respectfully requests that the rejections be removed.

Rejections under 35 U.S.C. § 103

The Examiner has additionally rejected claims 7, 8, 10-13, 16, and 19-21 under 35 U.S.C. § 103(a) as allegedly being obvious over Parunak. Applicant respectfully traverses the rejection.

The framework under which obviousness of a patent claim is judged was set forth by the U.S. Supreme Court in *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966), and is as follows. Under § 103:

- the scope and content of the prior art are to be determined;
- differences between the prior art and the claims at issue are to be ascertained; and
- the level of ordinary skill in the pertinent art resolved.

Based upon the answers to these factual enquiries, the obviousness or nonobviousness of the claimed subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might also be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.

Accordingly, and at a minimum, in order to establish obviousness of a claim, the prior art reference, or references when combined, must teach or suggest each and every limitation of the claimed invention. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Furthermore, and in instances where each and every limitation of the claimed invention can be found in a combination of references, an analysis of an apparent reason to combine the known elements in the fashion claimed should be made explicit. *See KSR Int'l. Co. v. Teleflex Inc.*, 550 U.S. 398 (2007).

Dependent claims are nonobvious under 35 U.S.C. § 103 "if the independent claims from which they depend are nonobvious." *In re Fine*, 837 F.2d 1071; 5 USPQ.2d 1596; MPEP § 2143.03.

Claims 7 and 8

The Examiner asserts that it would have been obvious to one of ordinary skill in the art to incorporate "recombining the retained particles with the subset of the first portion of the liquid" to remove the particles or cells from the filter or to prevent lysis of the cells at the filter interface because, allegedly, "it is well known in the art that filters will clog from the particles or cells adsorbing to the surface of the filter."

Applicant submits that such incorporation would not be possible with the device taught by Parunak. The pressure provided by the actuator of Parunak is not sufficient to cause liquid to flow back through the flow through member for a second time after particles or cells are retained thereon. In contrast, Applicant describes a pressure differential between a pressure of gas above fluid in a reservoir and a pressure downstream from the reservoir. This pressure differential draws a portion of the fluid present in the reservoir through the retention member and thereby combines with particles retained by the retention during sample introduction. (*See*, *e.g.*, Applicant's specification at 16, lines 25-33.)

Additionally, Parunak explicitly teaches away from recombining the retained particles with the subset of the first portion of the liquid as Parunak teaches that the enriched sample is moved downstream with essentially no dilution thereof. Recombining the retained particles with liquid would cause dilution of the sample.

Thus, for at least the foregoing reasons, Applicant submits that claim 7 and its respective dependent claim 8 are not obvious over Parunak.

Claims 10, 11, 12, and 13

The Examiner submits that it would have been obvious to one of ordinary skill in the art to modify the method of Parunak and include a plunger or diaphragm to reduce the pressure acting on the particles. Applicant respectfully disagrees for at least the reasons discussed with respect to claim 7. Furthermore, the claims as amended herein recite a syringe for introducing the sample not to reduce the pressure acting on the particles. Accordingly, Applicant further submits that dependent claims 11, 12, and 13 are similarly not obvious over Parunak.

Claim 16

The Examiner submits that it would have been obvious to one of ordinary skill in the art to incorporate "recombining the retained particles with the subset of the first portion of the liquid" to remove the particles or cells from the filter or to prevent lysis of the cells at the filter interface because, allegedly, it is well known in the art that filters will clog from the particles or cells adsorbing to the surface of the filter. Applicant respectfully disagrees for at least the reasons discussed with respect to claim 7.

Claim 19

The Examiner submits that it would have been obvious to one of ordinary skill in the art to use a temperature responsive mass because this would allow passage of the material of the lysing zone upon reaching a particular voltage. Applicant respectfully disagrees. Use of a temperature responsive mass in the device of Parunak (in place of a substance that is acted on by electrodes) would not result in Applicant's recited invention. As discussed hereinabove, Parunak teaches a responsive substance upstream of the lysing module. Heating of a temperature responsive substance in this configuration would not result in the downstream passage of material of the lysing zone, as alleged by the Examiner.

Claim 20

Applicant respectfully submits that claim 20 and its respective dependent claim 21 is not obvious over Parunak for at least the reasons discussed with respect to claim 7.

By responding in the foregoing remarks only to particular positions taken by the examiner, Applicant does not acquiesce with other positions that have not been explicitly addressed. In addition, Applicant's selecting particular arguments for the patentability of a claim should not be understood as implying that no other reasons for the patentability of that claim exist. Finally, Applicant's decision to amend or cancel any claim should not be understood as implying that the Applicant agrees with any positions taken by the Examiner with respect to that claim or other claims affected by such amendments.

CONCLUSION

In view of the above remarks, Applicant respectfully submits that the subject application is in good and proper order for allowance. Withdrawal of the Examiner's rejections and early notification to this effect are earnestly solicited. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is encouraged to call the undersigned at (650) 839-5070.

No fee is believed owed in connection with filing of this amendment and reply, other than the extension of time separately authorized herewith. However, should the Commissioner determine otherwise, the Commissioner is authorized to charge any underpayment or credit any overpayment to Fish & Richardson P.C. Deposit Account No. 06-1050 (Ref. No. 19662-0035US1) for the appropriate amount.

Respectfully submitted,

Date: June 1, 2009

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